

## § 868.6225

### § 868.6225 Nose clip.

(a) *Identification.* A nose clip is a device intended to close a patient's external nares (nostrils) during diagnostic or therapeutic procedures.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38796, July 25, 2001]

### § 868.6250 Portable air compressor.

(a) *Identification.* A portable air compressor is a device intended to provide compressed air for medical purposes, e.g., to drive ventilators and other respiratory devices.

(b) *Classification.* Class II (performance standards).

### § 868.6400 Calibration gas.

(a) *Identification.* A calibration gas is a device consisting of a container of gas of known concentration intended to calibrate medical gas concentration measurement devices.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

### § 868.6700 Anesthesia stool.

(a) *Identification.* An anesthesia stool is a device intended for use as a stool for the anesthesiologist in the operating room.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25049, June 12, 1989; 66 FR 38796, July 25, 2001]

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### § 868.6810 Tracheobronchial suction catheter.

(a) *Identification.* A tracheobronchial suction catheter is a device used to aspirate liquids or semisolids from a patient's upper airway.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 868.9.

[47 FR 31142, July 16, 1982, as amended at 65 FR 2314, Jan. 14, 2000]

### § 868.6820 Patient position support.

(a) *Identification.* A patient position support is a device intended to maintain the position of an anesthetized patient during surgery.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

### § 868.6885 Medical gas yoke assembly.

(a) *Identification.* A medical gas yoke assembly is a device intended to connect medical gas cylinders to regulators or needle valves to supply gases for anesthesia or respiratory therapy. The device may include a particulate filter.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

## PART 870—CARDIOVASCULAR DEVICES

### Subpart A—General Provisions

#### Sec.

##### 870.1 Scope.

##### 870.3 Effective dates of requirement for premarket approval.

##### 870.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

**Subpart B—Cardiovascular Diagnostic Devices**

- 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm).
- 870.1100 Blood pressure alarm.
- 870.1110 Blood pressure computer.
- 870.1120 Blood pressure cuff.
- 870.1130 Noninvasive blood pressure measurement system.
- 870.1140 Venous blood pressure manometer.
- 870.1200 Diagnostic intravascular catheter.
- 870.1210 Continuous flush catheter.
- 870.1220 Electrode recording catheter or electrode recording probe.
- 870.1230 Fiberoptic oximeter catheter.
- 870.1240 Flow-directed catheter.
- 870.1250 Percutaneous catheter.
- 870.1270 Intracavitary phonocatheter system.
- 870.1280 Steerable catheter.
- 870.1290 Steerable catheter control system.
- 870.1300 Catheter cannula.
- 870.1310 Vessel dilator for percutaneous catheterization.
- 870.1330 Catheter guide wire.
- 870.1340 Catheter introducer.
- 870.1350 Catheter balloon repair kit.
- 870.1360 Trace microsphere.
- 870.1370 Catheter tip occluder.
- 870.1380 Catheter stylet.
- 870.1390 Trocar.
- 870.1425 Programmable diagnostic computer.
- 870.1435 Single-function, preprogrammed diagnostic computer.
- 870.1450 Densitometer.
- 870.1650 Angiographic injector and syringe.
- 870.1660 Indicator injector.
- 870.1670 Syringe actuator for an injector.
- 870.1750 External programmable pacemaker pulse generator.
- 870.1800 Withdrawal-infusion pump.
- 870.1875 Stethoscope.
- 870.1915 Thermodilution probe.
- 870.2370 Electrocardiograph surface electrode tester.
- 870.2390 Phonocardiograph.
- 870.2400 Vectorcardiograph.
- 870.2450 Medical cathode-ray tube display.
- 870.2600 Signal isolation system.
- 870.2620 Line isolation monitor.
- 870.2640 Portable leakage current alarm.
- 870.2675 Oscillometer.
- 870.2700 Oximeter.
- 870.2710 Ear oximeter.
- 870.2750 Impedance phlebograph.
- 870.2770 Impedance plethysmograph.
- 870.2780 Hydraulic, pneumatic, or photoelectric plethysmographs.
- 870.2800 Medical magnetic tape recorder.
- 870.2810 Paper chart recorder.
- 870.2840 Apex cardiographic transducer.
- 870.2850 Extravascular blood pressure transducer.
- 870.2860 Heart sound transducer.
- 870.2870 Catheter tip pressure transducer.
- 870.2880 Ultrasonic transducer.
- 870.2890 Vessel occlusion transducer.
- 870.2900 Patient transducer and electrode cable (including connector).
- 870.2910 Radiofrequency physiological signal transmitter and receiver.
- 870.2920 Telephone electrocardiograph transmitter and receiver.

**Subpart D—Cardiovascular Prosthetic Devices**

- 870.3250 Vascular clip.
- 870.3260 Vena cava clip.
- 870.3300 Vascular embolization device.
- 870.3375 Cardiovascular intravascular filter.
- 870.3450 Vascular graft prosthesis.
- 870.3470 Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene.
- 870.3535 Intra-aortic balloon and control system.
- 870.3545 Ventricular bypass (assist) device.
- 870.3600 External pacemaker pulse generator.
- 870.3610 Implantable pacemaker pulse generator.
- 870.3620 Pacemaker lead adaptor.
- 870.3630 Pacemaker generator function analyzer.
- 870.3640 Indirect pacemaker generator function analyzer.
- 870.3650 Pacemaker polymeric mesh bag.
- 870.3670 Pacemaker charger.
- 870.3680 Cardiovascular permanent or temporary pacemaker electrode.
- 870.3690 Pacemaker test magnet.
- 870.3700 Pacemaker programmers.
- 870.3710 Pacemaker repair or replacement material.
- 870.3720 Pacemaker electrode function tester.
- 870.3730 Pacemaker service tools.
- 870.3800 Annuloplasty ring.

**Subpart C—Cardiovascular Monitoring Devices**

- 870.2050 Biopotential amplifier and signal conditioner.
- 870.2060 Transducer signal amplifier and signal conditioner.
- 870.2100 Cardiovascular blood flowmeter.
- 870.2120 Extravascular blood flow probe.
- 870.2300 Cardiac monitor (including cardiometer and rate alarm).
- 870.2310 Apex cardiograph (vibrocardiograph).
- 870.2320 Ballistocardiograph.
- 870.2330 Echocardiograph.
- 870.2340 Electrocardiograph.
- 870.2350 Electrocardiograph lead switching adaptor.
- 870.2360 Electrocardiograph electrode.

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- 870.3850 Carotid sinus nerve stimulator.
- 870.3925 Replacement heart valve.
- 870.3935 Prosthetic heart valve holder.
- 870.3945 Prosthetic heart valve sizer.

### Subpart E—Cardiovascular Surgical Devices

- 870.4075 Endomyocardial biopsy device.
- 870.4200 Cardiopulmonary bypass accessory equipment.
- 870.4205 Cardiopulmonary bypass bubble detector.
- 870.4210 Cardiopulmonary bypass vascular catheter, cannula, or tubing.
- 870.4220 Cardiopulmonary bypass heart-lung machine console.
- 870.4230 Cardiopulmonary bypass defoamer.
- 870.4240 Cardiopulmonary bypass heat exchanger.
- 870.4250 Cardiopulmonary bypass temperature controller.
- 870.4260 Cardiopulmonary bypass arterial line blood filter.
- 870.4270 Cardiopulmonary bypass cardiectomy suction line blood filter.
- 870.4280 Cardiopulmonary prebypass filter.
- 870.4290 Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting.
- 870.4300 Cardiopulmonary bypass gas control unit.
- 870.4310 Cardiopulmonary bypass coronary pressure gauge.
- 870.4320 Cardiopulmonary bypass pulsatile flow generator.
- 870.4330 Cardiopulmonary bypass on-line blood gas monitor.
- 870.4340 Cardiopulmonary bypass level sensing monitor and/or control.
- 870.4350 Cardiopulmonary bypass oxygenator.
- 870.4360 Nonroller-type cardiopulmonary bypass blood pump.
- 870.4370 Roller-type cardiopulmonary bypass blood pump.
- 870.4380 Cardiopulmonary bypass pump speed control.
- 870.4390 Cardiopulmonary bypass pump tubing.
- 870.4400 Cardiopulmonary bypass blood reservoir.
- 870.4410 Cardiopulmonary bypass in-line blood gas sensor.
- 870.4420 Cardiopulmonary bypass cardiectomy return sucker.
- 870.4430 Cardiopulmonary bypass intracardiac suction control.
- 870.4450 Vascular clamp.
- 870.4475 Surgical vessel dilator.
- 870.4500 Cardiovascular surgical instruments.
- 870.4875 Intraluminal artery stripper.
- 870.4885 External vein stripper.

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### Subpart F—Cardiovascular Therapeutic Devices

- 870.5050 Patient care suction apparatus.
- 870.5150 Embolectomy catheter.
- 870.5175 Septostomy catheter.
- 870.5200 External cardiac compressor.
- 870.5225 External counter-pulsating device.
- 870.5300 DC-defibrillator (including paddles).
- 870.5310 Automated external defibrillator.
- 870.5325 Defibrillator tester.
- 870.5550 External transcutaneous cardiac pacemaker (noninvasive).
- 870.5800 Compressible limb sleeve.
- 870.5900 Thermal regulating system.
- 870.5925 Automatic rotating tourniquet.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 45 FR 7907-7971, Feb. 5, 1980, unless otherwise noted.

### Subpart A—General Provisions

#### § 870.1 Scope.

(a) This part sets forth the classification of cardiovascular devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a pre-market notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a cardiovascular device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

[52 FR 17735, May 11, 1987, as amended at 68 FR 61344, Oct. 28, 2003]